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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,992	04/05/2001	Nurhan Pinar Tutuncu	2280.2660	3697

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FITZPATRICK CELLA HARPER & SCINTO  
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NEW YORK, NY 10112

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/825,992

Applicant(s)

TUTUNCU ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

Receipt of Request of Continued Examination and Preliminary Amendment C received on March 11, 2003 is acknowledged. Claims 1-24 are included in the prosecution of this application.

#### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on preliminary amendment C.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not provided support for more than one region of a salivating region and oral comforting region respectively. A careful examination of the specification only shows support for one salivating region and one oral comforting region.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-6, 8-12, 17, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP0407019.**

EP discloses a saliva-stimulating center-filled chewing gum. The gum base is made of sugar or sugarless gum. The gum base includes partially hydrogenated vegetable oil/animal fat (9%), monoglycerides, and emulsifiers (lecithin or GMO; see page, 11, lines 2) (8%). See page 3. Sucrose and corn syrup are preferred sugar bulking agents. See page 11, line 44. The center fill contains sugarless or sugar humectants, thickeners, and 1% flavoring agents. See page 22.

**Claims 1-3, 6-10, 13, 15-17, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Bealin-Kelly (6,306,429).**

Bealin-Kelly discloses a confectionary composition. The composition contains cooling and warming regions. The liquid, center filled candy drops contain 58.12% sucrose, 41.51% glucose syrup, 0.27% lemon oil, 0.17% menthol, and 0.19% citric acid. The filling contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin, 0.314%, and 0.16% color. See example 1. The regions are mixed separately and co-extruded.

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**Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanke et al (6,231,900).**

Hanke discloses preparation of a confectionary product to relieve cough (note abstract). Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The flavoring composition contains a gelatin sweetened mixture, 1.4% citric acid solution, colorant, and flavor. The cooling contains a sweetened agent, 0.7% citric acid, and menthol. Hanke discloses injecting the respective composition simultaneously into a mold. (Note example 1)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP0407019 in view of Parnell (4,983,378).**

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EP discloses a saliva-stimulating center-filled chewing gum. The gum base is made of sugar or sugarless gum. The gum base includes partially hydrogenated vegetable oil/animal fat (9%), monoglycerides, and emulsifiers (lecithin or GMO; see page, 11, lines 2) (8%). See page 3. Sucrose and corn syrup are preferred sugar bulking agents. See page 11, line 44. The center fill can contain various additives such as sweeteners, flavors, medicaments or mixtures. The center fill contains sugarless or sugar humectants, thickeners, and 1% flavoring agents. See page 22. Flavoring agents such as peppermint oil, clove oil, eucalyptus oil, citrus oil, etc. are taught. See page 13. EP states that saliva stimulating gums are known in the art and contain organic acids. See page 2, lines 42-46.

Although, EP discloses a saliva stimulating gum, it does not explicitly disclose the treatment of xerostomia. Further, EP does not exemplify an acid in the center-fill.

Parnell teaches a method and composition for treating xerostomia. Parnell teaches that xerostoma is a medical condition wherein the flow of saliva is inadequate to provide proper oral hygiene. See column 1, lines 10-15. Further, Parnell teaches the use of a stimulator compound to stimulate salivary gland secretion. Citric acid is taught as the preferred compound. See column 4, lines 43-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of EP and Parnell and utilize EP's composition to treat xerostomia. A skill artisan would be motivated to do so since xerostomia is a condition wherein an inadequate flow of saliva to the mouth exists and EP teaches a saliva stimulating composition; therefore a skilled artisan could

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reasonably expect treating xerostomia with EP's composition. Further, one would be motivated to look at the teachings of Parnell and incorporate an organic acid into the center-fill since Parnell teaches the use of organic acids stimulate saliva secretion. One would motivated to do so with the expectation of similar results since EP teaches a saliva stimulating composition and teaches the use of medicaments and flavor mixtures in the center-fill.

**Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bealin-Kelly (6,306,429).**

Bealin-Kelly discloses a confectionary composition. The composition contains cooling and warming regions. The liquid, center filled candy drops contain 58.12% sucrose, 41.51% glucose syrup, 0.27% lemon oil, 0.17% menthol, and 0.19% citric acid. The filing contains 84.3% high fructose corn syrup, 15% glycerin, 0.02% lecithin, 0.314%, and 0.16% color. See example 1. The vesicle-forming agent (lecithin) is taught in the amount of 0.001 to about 1%. See column 5, lines 20-21. The regions are mixed separately and co-extruded.

The reference does not exemplify the instant amount of surfactant/lipid.

It is deemed obvious to one of ordinary skill in the art to look to the teachings of Bealin-Kelly and utilize the surfactant/lipid in the instant amount. One would be motivated to do so since the reference teaches that lecithin may be used in an amount of 0.001 to 1% by weight. Therefore, a skilled artisan could reasonably expect similar results since Bealin-Kelly clearly teaches the suitability of the instant range.

**Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanke (6231900) by itself or in view of Klacik et al (6099880).**

Hanke discloses preparation of a confectionary product to relieve cough (note abstract). Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition to provide distinct releases. The flavoring composition contains a gelatin sweetened mixture, 1.4% citric acid solution, colorant, and flavor. The cooling contains a sweetened agent, 0.7% citric acid, and menthol. Hanke discloses the use of a mold in which the respective compositions are placed. (Note example 1)

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method to be a simple method. See column 1, lines 30-50.

In the absence of showing criticality, it is deemed obvious to one of ordinary skill in the art to manipulate Hanke's mold to further contain a ridge. One would be motivated to so since Hanke teaches a product having separate and distinct regions, thus adding a ridge to the mold would ensure further separation of the components.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to combine the Hanke and Klacik and utilize a mold with a ridge. One would be motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge.



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**Conclusion**

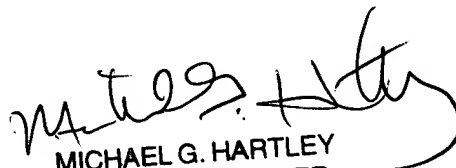
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

June 24, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER